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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,516	11/14/2001	David A. Shafer	D6431	8007

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11/06/2003

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/06/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,516

Applicant(s)

SHAFER, DAVID A.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 8 and 23-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION***Election/Restrictions******Response to Arguments***

Applicants argue that that the examiner's assertion of performing the claimed processes by hand is not reasonable. Applicants further argue that the method is not drawn to the making of macroarrays or microarrays. The miniarray of the present invention contains hundreds or thousands of assay spots, not a few dozen spots per array. It is not reasonable and practical to make hundreds or thousands of assay spots by hand. It is further argue that Figure 5 is meant to demonstrate using pipettes to lead and dispense microliter and nanoliter quantities of reagents respectively by capillary action. Figure 5 is not an embodiment of the present invention.

In reply, whether it is not reasonable or impractical to make a miniarray by hand is irrelevant to the restriction between two distinct and different methods. The method of making by hand as indicated in **Figure 5** of the Drawings is another means or distinct method by which a miniarray can be fabricated. Figure 5 clearly label a "hand spotted miniarray". Furthermore, whether Figure 5 is not an embodiment of the present invention is immaterial. Restriction is based on whether distinct and independent inventions are present in the application. Since

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applicants clearly acknowledge in Figure 5 that a miniarray can be made by hand, hence the method of making miniarray by hand is distinct and independent from the argued apparatus.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6, 8 and 23-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Status of Claims

Claims 1-54 are pending in the application.

Claims 1-6, 8 and 23-54 are withdrawn from consideration, as stated above.

Claims 7 and 9-22 are under consideration.

Specification

The disclosure is objected to because of the following informalities for reasons advanced in the last Office action.

Response to Arguments

A. In view of the amendments to the specification, the objection of the specification has been obviated

Applicants' amendments to the various part of the specification have not been entered. There is no positive

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request or direction to enter these various amendments.

Applicants' statement that the specification "has been amended as follows" is not a positive request or direction to enter the amendments to the specification.

B. Applicants' argument with respect to the correctness of U.S. Pat. No. 6,001,309 obviates the objection of the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 9-22 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The as-filed specification does not describe a method of making miniarray with spots or location of **about 0.5 mm to about 3 mm**. The as-filed specification recites the spots or locations of 1 and 3 mm CTC. There is no description as to a spot of about 0.5 mm or the minimum or maximum range of about 3 mm CTC.

MPEP 714.02 recites that applicants specifically point out where in the specification the newly added limitation appears.

Claim Rejections - 35 USC § 112. second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 9-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In view of applicants' amendments to the claims, the rejection of the claims under this statute no longer applies.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 7, 9-10, 12-22 under 35 U.S.C. 102(e) as being anticipated by Balch (U.S.6,083,763) or Lockhart et al (6,040,38) and Brown (102b) no longer applies with the amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Amended claims 7 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Lange, (abstract) for reasons advanced in the last Office action or over Van Ness et al (6,248,521) in view of Lange.

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Response to Arguments

Applicants admit that Brown teach a microarray having assay spots 20-200um in diameter and center to-center spacing in the range of 20-400 um. But argue that the high density microarrays of Brown is different and distinct from the miniarray of the claimed invention.

In reply, the recited spacing of Brown of 400 um approximates the claimed about 5 mm CTC spacing of spots. Furthermore, the CTC spots or locations are not a fixed parameter, rather is a variable that can be varied as shown by the prior art and depending upon the variation in the diameter of the spots dispensed by the pipettes. Brown recites 20-400 um as an example and not as an absolute value. CTC is a result effective variable well within the realm of one having ordinary skill in the art. Applicants' arguments with respect to the high density of the claimed miniarray are a limitation not appearing in the claims (and unclear whether this is based on CTC). Thus since Brown CTC approximates the instant claimed about .5 mm the claimed miniarray is prima facie obvious over the teachings of Brown.

Applicants' admit that Lange teaches a contamination-free device for pipetting liquid, said device comprises a reusable dispensing element and a disposable double tip. Accordingly, to

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use a disposable pipette tip in the method of Brown will be prima facie obvious to one having ordinary skill in the art.

Van Ness basically discloses the same or similar method as Brown above. Van Ness further discloses at col. 6, lines 54-60 a CTC spots of 25-500 um. Thus, Van Ness clearly teaches that CTC is a result effective variable that can be varied depending upon factors such as the desired diameter of the spots dispensed and etc.

Each of the Balch or Lockhart references no longer applies with the amendments to the claims.

No claims are allowed.

Response to Arguments

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

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statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

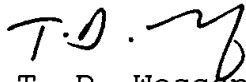
This application contains claims 1-6, 8 and 23-54 are drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
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tdw

October 30, 2003